Study Title: Radiographic Evaluation of Delayed Solid Organ Complications Multicenter Trial

Short Title: REDSOC

Principal Investigator: Lindsey Perea, DO

Co-Investigators: Madison Morgan, BS; Kellie Bresz, MS

Principal Site: Penn Medicine Lancaster General Health

Key Roles and Study Governance:

Lindsey Perea, DO: Principal Investigator

Madison Morgan: Research Coordinator

Kellie Bresz: Statistical Support

Protocol Date: 3/23/2021

Background & Significance

Non-operative management of splenic and hepatic injuries has become one of the standards of care in the management of hemodynamically stable patients. Institutional variance exists in management of these injuries regarding serial laboratory values, transfusion thresholds, the utility of interventional radiology/operative management, follow up imaging, and management of delayed findings on this imaging. The delayed complications found both clinically and with follow up imaging vary in the literature from nearly 0% to >15% of cases. There is no clear evidence as to the necessity of repeat imaging or frequency of intervention in blunt splenic and hepatic injuries. Some studies recommend only follow up

imaging for high grade injuries, whereas other studies have found no correlation between grade of injury and complications.

Our group approached this question through a dual institution, retrospective pilot study observing the management of delayed splenic and hepatic complications found on repeat imaging. This study was performed in the adult population and a current study is ongoing in the pediatric population. Imaging was obtained either via the institutions standard protocol (SP) or physician discretion (PD) (lab or vital sign abnormalities, clinical change, etc). There were 235 splenic injuries with 45% undergoing repeat imaging. 64% of these were due to PD. Complications were found in 47% of SP and 42% of PD patients (p=0.683). Interventions performed for these complications was done for 56% SP v. 21% of PD patients (p=0.027). This pilot study suggested that patients with blunt splenic injuries should undergo repeat imaging for delayed complications and that those who underwent repeat imaging by SP had complications identified sooner (2.4 v 4.4 days) and treated earlier than the PD group.

Of the 365 liver injuries, 33.4% underwent repeat imaging with a majority (59%) of these due to physician discretion. Complications were found in 20% of SP patients and 27% of PD patients (p=0.395). Interventions were performed in 20% SP v. 25% PD patients that had complications (p=1.00). In the liver injury group there was no difference found between complications or interventions performed when assessed by SP or PD; waiting to perform repeat imaging based on PD could prevent unnecessary imaging in blunt liver injuries.

In this small pilot study we were unable to achieve all of our primary and secondary endpoints. Additionally, interventions in low grade injuries are uncommon, and a larger data set would allow for delineation in management between low, moderate and high grade splenic and hepatic injuries. This study did not have power due to a limited number of patients receiving interventions, thus making characterization of types of interventions and final outcomes difficult.

A large multicenter trial would allow for appropriate power for the study and thus allow for us to meet our endpoints. There are multiple variables affecting the management of blunt splenic and hepatic injuries and currently no clear guidelines exist in regards to repeat imaging. Gaining a better understanding of types of delayed complications, how they present, and current management strategies would assist in creating a standardized algorithm in the treatment of this patient population.

Specific Aims of Multicenter Study

Aim 1: To define which blunt splenic and hepatic injuries are at risk of delayed complications in order to develop a societal management guideline.

Aim 2: To ascertain which patients warrant repeat imaging and when this imaging should be performed.

Aim 3: To define what interventions are needed based upon delayed complications found radiographically.

Aim 4: To analyze 30 day readmission rates to the hospital due to spleen and/or liver injury.

Methods

This will be a retrospective observational study. Patients will be managed according to the surgeon's discretion. The study will enroll a total of 5,000 subjects at minimum. This study plans to enroll 200 patients at our institution, Penn Medicine Lancaster General Health. The number of subjects that will be enrolled at each additional participating site is 200.

Inclusion Criteria**:**

- All patients (all ages) who present with blunt trauma to the spleen and/ or liver

Exclusion Criteria**:**

- Patients who suffer a penetrating mechanism
- Patients transferred out to another facility prior to admission

Updated Terms/Definitions:

- **Clinical Change (CC) (to replace Physician Discretion)-** repeat imaging prompted by patient factors including vital sign changes, lab abnormalities, abdominal pain, and patient symptoms

- **Non Clinical Change (NCC) (to replace Standard Protocol)-** repeat imaging prompted by institutional protocol/ recommendations, individual physician practice pattern, or that performed on a scheduled basis

The time frame for data query will be from IRB approval (2020) until December 31, 2023. The electronic medical record (EMR) may be used in order to identify participants who match study defined demographic criteria.

Primary Outcome**:** Delayed complications found on repeat imaging

Secondary Outcomes**:** Timing to repeat imaging/ intervention, interventions performed based on complications found, mortality, length of stay, blood transfusion requirements, VTE prophylaxis, and 30 day readmission variables [readmission within 30 days for spleen and/or liver injury, readmission CT scan, interventions performed].

Variables

List specific variables to be collected & analyzed**:** Age, sex, time from injury, Injury Severity Score (ISS), Abbreviated Injury Scale (AIS), Trauma and Injury Severity Score (TRISS), mechanism of injury, initial vital signs, anticoagulant use and reversal agents, initial and repeat imaging, grade of organs injured, complications found, details regarding initial and any delayed interventions, blood transfusions, details regarding venous thromboembolism prophylaxis, venous thromboembolism complications, hospital length of stay, intensive care unit length of stay, mortality, and 30 day readmission variables [readmission within 30 days for spleen and/or liver injury, readmission CT scan, interventions performed].

Data Collection and Statistical Analysis

Standardized data will be collected for each patient meeting inclusion criteria (see data collection tool). The de-identified data for each patient will be entered into a secure REDCap database. A total of 5,000 patients (3,500 splenic injuries and 1,500

hepatic injuries) is recommended to identify a significant difference between the non clinical change and clinical change group. Complications found on repeat imaging will be assessed using univariate and multivariate analysis.

Categorical variables will be compared using Fisher's exact test or Chi-squared test. Continuous variables will be assessed using Student's t-test. For multivariate analysis, a mixed effect multinomial logistic regression will be run with a binary outcome of whether the patient had a delayed complication. Another mixed effect multinomial logistic regression will be run with a binary outcome of whether the patient had an intervention performed. Additional analysis will be completed to determine if there is optimal timing for repeat imaging to identify complications. Data will be reported as adjusted odds ratios with 95% confidence intervals. Statistical significance will be defined by a $p<0.05$.

Sample Size and Power Estimates

A retrospective pilot study was completed with 235 patients with splenic injuries and 365 hepatic injuries. Of the patients with splenic injuries, 105 underwent repeat imaging, 46 had organ specific complications, and 16 had an intervention performed. Of the patients with hepatic injuries, 122 underwent repeat imaging, 30 had organ specific complications, and 12 had an intervention performed.

Spleen Power Analysis

Combined complication rate for patients who had repeat imaging: 46/105 = 0.44
Standard protocol complication rate: 18/38 = 0.47
Physician discretion complication rate: 28/67 = 0.42

Complication Rate: Standard protocol	Complication Rate: Physician discretion	Odds Ratio	Sample Size (Total Population)
0.46	0.43	0.89	8,614
0.47	0.42	0.82	3,100
0.48	0.41	0.75	1,582

Liver Power Analysis

Combined complication rate for patients who had repeat imaging: 30/122 = 0.25
Standard protocol complication rate: 10/50 = 0.20
Physician discretion complication rate: 20/72 = 0.27

Complication Rate: Standard protocol	Complication Rate: Physician discretion	Odds Ratio	Sample Size (Total Population)
0.21	0.26	1.32	2,256
0.20	0.27	1.48	1,150
0.19	0.28	1.66	696

Consent Procedures

This is a retrospective observational study in which data will be retrospectively recorded on patients according to institutional protocols. Data will be input into REDcap database without any patient identifiers. Thus, a waiver of consent is requested.

Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible.

Authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), regulatory agencies or pharmaceutical company supplying study product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for 6 years as dictated by the HRPP.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the on secure servers or in REDCap, a HIPAA compliant database management system. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at Lancaster General Health Research Institute.

Risks and Adverse Event Reporting

The data collected and transferred to REDcap for the multicenter trial would be devoid of any patient identifiers and thus is a low risk study. The only risk to the subject is a confidentiality breach associated with their data being accessed and included as part of this retrospective chart review. However, this study only contained de-identified data entered into the REDCap. If an adverse event occurs, once investigators have learned of this, the IRB will be notified within 48 hours.

Potential Benefits

The benefit would be to improve clinical practice as the incidence and characterization of delayed complications in blunt solid organ injury is not well understood. Additionally, understanding types of delayed complications, when they are identified, and if/ how they are treated will allow for more definitive guidelines and improved outcomes for this population of patients.

Risk/ Benefit Analysis

This study is no more than minimal risk since it is a retrospective observational study that does not contain any patient identifiers

Waiver of Consent and HIPAA

We are seeking a waiver of consent and HIPAA authorization for this study.

Waiver or alteration of required elements of consent: According to HHS CFR 45.46.116(d): An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent. This study qualifies for a waiver of informed consent due to each of the following:

- This study is no more than minimal risk to subjects: there is no intervention or interaction with subjects, it is observational in nature and will only involve medical chart review.
- The waiver or alteration would not adversely affect the rights and welfare of the subjects: rights and welfare of the subjects will not be adversely impacted

as this study is similar to many other retrospective observational studies. No subjects will be identified individually.

- The research could not practicably be carried out without the waiver or alteration: the attempt to contact subjects poses a greater risk than this study. It would be impractical to contact subjects as data collection occurs retrospectively, well after the patient is discharged from the hospital, and to contact subjects, would require patient identifiers, which are not provided by the data sources.
- Where appropriate, subjects will be provided with additional: there are no plans to contact subjects as it is not necessary to the analysis of this study.

For the waiver of HIPAA:

- This study poses no more than minimal risk to privacy: will protect identifiers from improper use and disclosure; will de-identify data prior to sharing with other institutions. Each of the study sites is assigned a site identifier to maintain privacy. Please note that each study site can only access data pertaining to their site alone on REDCap. However, only the lead site (Penn Medicine LGH) principal investigator (Dr. Perea) has the ability to link specific study institutions with their data.

Conflict of Interest Policy

All Investigators will follow the Penn Medicine Lancaster General Health Policy on Conflicts of Interest Related to Research.

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

Publication Plan

After completion of the study and analysis and interpretation of the data, a manuscript for publication will be written with the principal investigator as the lead author. The sub-investigators will be listed in order of effort dedicated to the study. The manuscript will be targeted for publication in trauma or critical care journal.

References

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as this study is similar to many other retrospective observational studies. No subjects will be identified individually.

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References

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Penn Medicine
Lancaster General Hospital

INSTITUTIONAL REVIEW BOARD

April 12, 2021

Lindsey Perea, DO
Penn Medicine LGHP Trauma and Acute Care Surgery
2106 Harrisburg Pike Suite 322
Lancaster, PA 17601-2644

RE: **REDSOC:** Radiographic Evaluation of Delayed Solid Organ Complications Multicenter Trial
Protocol Number: 2020-82

Dear Dr. Perea:

On April 9, 20021, a designee of the Chair of the Institutional Review Board of the Lancaster General Hospital conducted an expedited review of the revised protocol, Version 3, dated March 23, 2021 for above-mentioned exempt research project. Pursuant to 45 CFR § 46.110, this review revealed minimal changes, which did not represent an increased risk to subjects. The amendment does not change the exempt status of the protocol from review by the Lancaster General Hospital IRB. The project continues to be exempt per 45 CFR § 46.104(d)(4).

The project approval period continues: April 9, 2021 – November 2, 2023. You may request an extension of the approval period if necessary. Please notify the Institutional Review Board of any further revisions.

Sincerely,

Doreen W. Bett, DO/tp

Doreen W. Bett, DO
Chair, Institutional Review Board

DWB:tp

Institutional Review Board
555 North Duke Street | P.O. Box 3555 | Lancaster, PA 17604-3555 | Office: 717-544-5091 | Fax: 717-544-1781
Antoinette.Phelan@pennmedicine.upenn.edu

Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST MULTICENTER STUDY
DATA COLLECTION TOOL

Multicenter Study: _____

Enrolling Center: _____
Enrolling Co-investigator: _____

Demographic Variables

Age: _____ Sex: _____ Weight (kg): _____

Description of Initial Injury

Estimated time from injury to presentation (in hours): _____

ISS: _____ AIS Head/Neck: _____ AIS Face: _____ AIS Chest: _____

AIS Abdomen/Pelvis: _____ AIS Extremity: _____ AIS External: _____

TRISS: _____

Mechanism of Injury (check one that best applies):

_____ Fall
_____ Motor Vehicle Crash
_____ Bicycle
_____ Pedestrian Struck
_____ Assault (by person or animal)
_____ Crush Injury
_____ Motorcycle Crash/All-Terrain Vehicle (ATV) Crash
_____ Non-accidental Trauma (NAT)
_____ Sports Injury
_____ Other/Unknown

Vital Signs on Presentation

SBP: _____ HR: _____ SpO2: _____ GCS: _____

Admission Anticoagulation and Reversal:

Admission anticoagulation or antiplatelet therapy (defined as a patient home medication or present at time of initial assessment) (Circle one): YES NO

Admission Anticoagulation and Reversal (continued)

Anticoagulation/Antiplatelet agent (check all that are present at time of initial trauma assessment):

_____	Warfarin	_____	Rivaroxaban
_____	Apixaban	_____	Dabigatran
_____	Aspirin	_____	Clopidogrel
_____	Ticagrelor	_____	Other

Reversal agents given (defined as a reversal agent given for anticoagulation or antiplatelet therapy present during initial trauma assessment) (Circle one): YES NO

Reversal agent (check all that were given for reversal of anticoagulation/antiplatelet therapy):

_____	K centra	_____	Andexanet
_____	Idarucizumab	_____	Vitamin K
_____	FFP	_____	Other

Patient with coagulopathy present on admission? (Circle one): YES NO

Patient Initial INR: _____

Initial Imaging/Injury Assessment

Was an initial FAST performed? (Circle one):
YES YES/positive YES/negative NO

Which area of the FAST was positive? (Check all that apply):
_____ Pericardial
_____ Right upper quadrant
_____ Left upper quadrant
_____ Suprapubic

Was an initial CT scan performed? (Circle one):
YES NO After emergent OR

Organs Injured (Circle one):
LIVER SPLEEN BOTH (Liver and spleen)

Grade of Liver (Circle one): 1 2 3 4 5 6

Grade of Spleen (Circle one): 1 2 3 4 5

Repeat Imaging

Was repeat imaging performed? (Circle one): YES NO

If yes, CT or US? (Circle one): CT US

Time from initial presentation in hours: _____

Reason for repeat imaging (Check one):
_____ Clinical Change (change in patient status, vitals, labs, etc.)
_____ Non-Clinical Change (institutional recommendation, scheduled imaging)

Imaging Findings: _____

Organ Specific Delayed Complications

Liver Complications (defined as complications found during hospital admission, check all that apply):

_____ Increased bleeding/increased hemoperitoneum
_____ Pseudoaneurysm
_____ Hemobilia
_____ New area of hepatic injury not previously recognized on initial workup
_____ Hepatic infarct (not post intervention)
_____ Abscess
_____ Fulminant liver failure
_____ Bile leak/biloma
_____ Unexpected thrombosis (of hepatic and related vessels)
_____ Need for OR/intervention other than initial
_____ Other: _____

Spleen Complications (defined as complications found during hospital admission, check all that apply):

_____ Increased bleeding/increased hemoperitoneum
_____ Pseudoaneurysm
_____ Delayed rupture
_____ New area of splenic injury not previously recognized on initial workup
_____ Splenic infarct (not post intervention)
_____ Abscess
_____ Unexpected thrombosis (of splenic and related vessels)
_____ Pancreatic fistula
_____ Arteriovenous fistula
_____ Need for OR/intervention other than initial
_____ Other: _____

Intervention Information

Initial Intervention (prior to repeat imaging, circle one): YES NO

Time from initial presentation in hours: _____

Type of intervention (check one):

_____ OR (damage control? _____)
_____ IR
_____ Other: _____

What was performed? _____

Post-Imaging Intervention (following repeat imaging, circle one): YES NO

Time from initial presentation in hours: _____

Type of intervention (check one):

_____ OR
_____ IR
_____ Other: _____

What was performed? _____

Intervention Information (continued)

Was there a complication from an intervention (occurring during hospitalization)? Check all that apply:

_____ Migration of coil
_____ Rupture of vessel
_____ Pancreatic fistula post-splenectomy
_____ Abscess
_____ Need for repeat intervention/surgery
_____ Other: _____

Transfusion Information Total refers to sum of product during admission. Record in both units and volume (ml).

Transfusion during hospital admission? (circle one): YES NO

4h whole blood (units/ml): _____ 4h pRBC (units/ml): _____ 4h FFP (units/ml): _____

4h platelet (packs/ml): _____ 24h whole blood (units/ml): _____ 24h pRBC (units/ml): _____

24h FFP (units/ml): _____ 24h platelet (packs/ml): _____

Total whole blood (units/ml): _____ Total pRBC (units/ml): _____

Total FFP (units/ml): _____ Total platelet (packs/ml): _____

VTE prophylaxis:

Did patient receive VTE prophylaxis during admission? (Circle one): YES NO

Timing of initiation of VTE prophylaxis from initial presentation in hours: _____

Type of VTE prophylaxis (Check one):

_____ Enoxaparin
_____ Subcutaneous heparin
_____ Other: _____

VTE documented? (Circle one): YES NO

Type of VTE documented (Check one):

_____ Pulmonary embolism (PE)
_____ Deep Vein Thrombus (DVT)
_____ Other: _____

Did the patient receive therapeutic anticoagulation during their hospital admission? (Circle one): YES NO

Therapeutic Anticoagulation agent: _____

Outcome Data:

Hospital LOS: _____

ICU LOS: _____

Mortality (Circle one): YES NO

Mortality timing from admission (in days): _____

Outcome Data (continued):

Readmission within 30 days (Circle one): YES NO

Readmission CT scan (Circle one): YES NO

Readmission CT scan findings (organ specific): _____

Organ Specific Intervention Performed on Readmission (Circle one): YES NO

Reason for Intervention on Readmission: _____

Type of Intervention on Readmission: _____

Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST MULTICENTER STUDY
DATA DICTIONARY

Radiographic Evaluation of Delayed Solid Organ Complications – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
Demographic Variables	
Age	Age of patient enrolled.
Sex	Sex of patient enrolled.
Weight	Weight of patient enrolled in kilograms.
Description of Initial Injury	
Estimated Time from Injury	Numerical value for time from injury to presentation at hospital (in hours). If unknown, 1 hour will be selected.
ISS	Numerical value for calculated ISS (ISS = Injury Severity Score)
AIS Head/Neck	Numerical Value for AIS body region = Head/Neck (AIS = Abbreviated Injury Score)
AIS Face	Numerical Value for AIS body region = Face (AIS = Abbreviated Injury Score)
AIS Chest	Numerical Value for AIS body region = Chest (AIS = Abbreviated Injury Score)
AIS Abdomen/Pelvis	Numerical Value for AIS body region = Abdomen/Pelvis (AIS = Abbreviated Injury Score)
AIS Extremity	Numerical Value for AIS body region = Extremity (AIS = Abbreviated Injury Score)
AIS External	Numerical Value for AIS body region = External (AIS = Abbreviated Injury Score)
TRISS	Numerical Value for calculated TRISS (TRISS = Trauma Injury Severity Score)

Description of Initial Injury (continued)

Mechanism of Injury	Single choice for best description of blunt mechanism (exclude penetrating mechanisms) Options include: Fall Motor Vehicle Crash Bicycle Pedestrian Struck Assault (by person or animal) Crush Injury Motorcycle Crash/All-Terrain Vehicle (ATV) Crash Non-accidental Trauma (NAT) Sports Injury Other/Unknown

Vital Signs on Presentation

Initial SBP	Numerical Value for initial SBP (SBP = systolic blood pressure)
Initial HR	Numerical Value for initial HR (HR = heart rate)
Initial SpO2	Numerical Value for initial SpO2 (SpO2 = oxygen saturation)
Initial GCS	Numerical value for initial GCS score (GCS = Glasgow Coma Scale)

Admission Anticoagulation and Reversal

Admission Anticoagulation/Antiplatelet	Yes/No dropdown menu. Yes = patient on anticoagulation and/or antiplatelet therapy at time of admission. No = no anticoagulation or antiplatelet therapy at time of admission.
Anticoagulation/Antiplatelet Agent	If yes checked for Admission Anticoagulation/Antiplatelet, description of anticoagulation/antiplatelet agent which was present on admission. Check all that apply: Warfarin Rivaroxaban Apixaban Dabigatran Aspirin Clopidogrel Ticagrelor Other
Reversal Agents Given	Yes/No dropdown menu. Yes = reversal for anticoagulation given. No = no reversal agents given.

Admission Anticoagulation and Reversal (continued)

Reversal Agent	If yes checked for Reversal Agents Given, description of reversal agents used. Check all that apply: K centra Andexanet Idarucizumab Vitamin K FFP Other
Patient History of Coagulopathy	Yes/No dropdown menu. Yes = Patient with history of coagulopathy on admission. No = Patient with no history of coagulopathy on admission.
Initial INR	Numerical value for patient's INR on admission. (INR = International Normalized Ratio)

Initial Imaging

Initial FAST	Single choice for initial Focused Assessment with Sonography for Trauma (FAST). Options include: Yes: FAST performed on initial assessment, results not available. Yes/positive: FAST performed on initial assessment and positive defined by fluid present in at least one of four views. Yes/negative: FAST performed on initial assessment and negative defined by no fluid present in any of the four views. No: FAST not performed on initial assessment.
Area of FAST positive	If Yes/positive checked for Initial FAST, description of area of FAST which is positive. Check all that apply: Pericardial Right Upper Quadrant Left Upper Quadrant Suprapubic
Initial CT	Single choice for initial computed tomography (CT) scan of the abdomen/pelvis. Options include: Yes: CT scan performed on initial assessment. No: CT scan not performed on initial assessment. After emergent operating room (OR): CT scan performed after patient underwent emergent operation.

Initial Imaging (continued).

Organs Injured	Single choice for organ injuries identified on initial CT scan or within OR if occurred before imaging. Options include: Liver: Hepatic injury of any grade present on initial CT scan or found in OR at initial emergent operation. Spleen: Splenic injury of any grade present on initial CT scan or found in OR at initial emergent operation. Both: Hepatic AND splenic injuries of any grade present on initial CT scan or found in OR at initial emergent operation.
Grade of Liver	Single choice for grade of hepatic injury following AAST grading scale. If no hepatic injury present, leave blank. Note: Advance one grade for multiple hepatic injuries up to grade 3. Options include: Grade 1: Subcapsular hematoma <10% surface area. Parenchymal laceration <1 cm in depth. Grade 2: Subcapsular hematoma 10-50% surface area; intraparenchymal hematoma <10 cm diameter. Laceration 1-3 cm depth and <10 cm length. Grade 3: Subcapsular hematoma >50% surface area; ruptured subcapsular or parenchymal hematoma. Intraparenchymal hematoma >10 cm. Laceration > 3 cm depth. Any injury in the presence of a liver vascular injury or active bleeding contained within liver parenchyma. Grade 4: Parenchymal disruption involving 25-75% of a hepatic lobe. Active bleeding extending beyond the liver parenchyma into the peritoneum. Grade 5: Parenchymal disruption >75% of hepatic lobe. Juxtahepatic venous injury to include retrohepatic vena cava and central major hepatic veins. Grade 6: Hepatic avulsion.
Grade of Spleen	Single choice for grade of splenic injury following AAST grading scale. If no splenic injury present, leave blank. Note: Advance one grade for multiple splenic injuries up to grade 3. Options include: Grade 1: Subcapsular hematoma <10% surface area. Parenchymal laceration <1 cm depth. Capsular tear. Grade 2: Subcapsular hematoma 10-50% surface area; intraparenchymal hematoma <5 cm. Parenchymal laceration 1-3 cm depth. Grade 3: Subcapsular hematoma >50% surface area; ruptured subcapsular or intraparenchymal hematoma ≥5 cm. Parenchymal laceration >3 cm depth.

	Grade 4: Any injury in the presence of a splenic vascular injury or active bleeding confined within the splenic capsule. Parenchymal laceration involving segmental or hilar vessels producing >25% devascularization. Grade 5: Any injury in the presence of splenic vascular injury with active bleeding extending beyond the spleen into the peritoneum.
Repeat Imaging	
First Repeat Imaging	Yes/No dropdown menu. Yes = Repeat abdominal imaging performed during same hospital admission. No = No additional abdominal imaging performed during same hospital admission.
First Repeat Imaging Type	If yes checked for First Repeat Imaging, single choice for type of repeat imaging. Options include: Computed Tomography (CT) Ultrasound (US)
First Repeat Imaging Hours from Admission	If yes checked for First Repeat Imaging, numerical value for when repeat imaging was performed in hours from admission.
Reason for First Repeat Imaging	If yes checked for First Repeat Imaging, single choice for best reason for scan. Options include: Clinical Change: Repeat imaging prompted by patient factors including, but not limited to, vital sign changes, lab abnormalities, abdominal pain, and patient symptoms. Non-Clinical Change: Repeat imaging prompted by institutional protocol/recommendations, individual physician practice pattern, or that performed on a scheduled basis.
First Repeat Imaging Findings	If yes checked for First Repeat Imaging, free text of organ specific (hepatic or splenic) imaging findings.
Organ Specific Delayed Complications	
Liver Complications	Liver specific complications found during hospital admission. Check all that apply. Options include: Increased bleeding, including increased hemoperitoneum. Pseudoaneurysm Hemobilia New area of hepatic injury not previously recognized on initial workup. Hepatic infarct (not post-IR/post-intervention). Abscess Fulminant liver failure Bile leak/biloma Unexpected thrombosis (of hepatic and related vessels) Need for OR/intervention other than initial Other (free text)

Organ Specific Delayed Complications (continued)

Spleen Complications	Spleen specific complications found during hospital admission. Check all that apply. Options include: Increased bleeding, including increased hemoperitoneum. Pseudoaneurysm Delayed rupture. New area of splenic injury not previously recognized on initial workup. Splenic infarct (not post-IR/post-intervention). Abscess Unexpected thrombosis (of splenic and related vessels) Pancreatic fistula Arteriovenous fistula Need for OR/intervention other than initial Other (free text)

Intervention Information

Initial Intervention	Intervention for hepatic and/or splenic injury prior to repeat imaging (can occur post-initial imaging assessment). Yes/No dropdown menu. Yes = intervention performed for hepatic and/or splenic injury at initial assessment, prior to repeat imaging. No = no intervention performed for hepatic and/or splenic injury at initial assessment, prior to repeat imaging.
Initial Intervention Timing	If yes checked for Initial Intervention, numerical value for time to intervention from presentation (in hours).
Initial Intervention Type	If yes checked for Initial Intervention, single best choice for type of intervention performed. Options include: OR: Patient taken to operating room. Damage Control: Operation specifically described as damage control or patient described as unstable. Planned OR: Operation on stable patient. Interventional Radiology (IR): Patient taken to IR suite for intervention. Other
Initial Intervention Description	If yes checked for Initial Intervention, free text briefly describing organ specific (hepatic or splenic) intervention.
Post-Imaging Intervention	Intervention for hepatic and/or splenic injury following repeat imaging (as a result of the imaging findings). Yes/No dropdown menu. Yes = intervention performed for hepatic and/or splenic injury following repeat imaging. No = no intervention performed for hepatic and/or splenic injury following repeat imaging.
Post-Imaging Intervention Timing	If yes checked for Post-Imaging Intervention, numerical value for time to intervention from presentation (in hours).

Intervention Information (continued)

Post-Imaging Intervention Type	If yes checked for Post-Imaging Intervention, single best choice for type of intervention performed. Options include: OR: Patient taken to operating room. Interventional Radiology (IR): Patient taken to IR suite for intervention. Other
Post-Imaging Intervention Description	If yes checked for Post-Imaging Intervention, free text briefly describing organ specific (hepatic or splenic) intervention.
Intervention Complication	Complications of organ specific (hepatic or splenic) interventions which occurred during the hospitalization. Check all that apply. Leave blank if no complications of interventions found. Migration of coil Rupture of vessel Pancreatic fistula post-splenectomy Abscess Need for repeat intervention/surgery Other (free text)

Transfusion Information

Transfusions	Yes/No dropdown menu for transfusions during hospital admission. Yes = patient received blood products (whole blood, pRBCs, FFP, platelets) during hospital admission. No = patient did not receive blood products during hospital admission.
4h Whole Blood Total Units	Total units of Whole Blood administered in the first 4 hours (4h) from presentation.
4h pRBC Total Units	Total units of Packed Red Blood Cells (pRBC) administered in the first 4 hours (4h) from presentation.
4h FFP Total Units	Total units of Fresh Frozen Plasma (FFP) administered in the first 4 hours (4h) from presentation.
4h Platelet Total Packs	Total packs of Platelets administered in the first 4 hours (4h) from presentation.
24h Whole Blood Total Units	Total units of Whole Blood administered in the first 24 hours (24h) from presentation.
24h pRBC Total Units	Total units of Packed Red Blood Cells (pRBC) administered in the first 24 hours (24h) from presentation.
24h FFP Total Units	Total units of Fresh Frozen Plasma (FFP) administered in the first 24 hours (24h) from presentation.
24h Platelet Total Packs	Total packs of Platelets administered in the first 24 hours (24h) from presentation.

Transfusion Information (continued)

Total Whole Blood Units	Total units of Whole Blood administered during hospital admission.
Total pRBC Units	Total units Packed Red Blood Cells (pRBC) administered during hospital admission.
Total FFP Units	Total units Fresh Frozen Plasma (FFP) administered during hospital admission.
Total Platelet Packs	Total packs of Platelets administered during hospital admission.
4h Whole Blood Total Volume	Total volume in ml of Whole Blood administered in the first 4 hours (4h) from presentation.
4h pRBC Total Volume	Total volume in ml of Packed Red Blood Cells (pRBC) administered in the first 4 hours (4h) from presentation.
4h FFP Total Volume	Total volume in ml of Fresh Frozen Plasma (FFP) administered in the first 4 hours (4h) from presentation.
4h Platelet Total Volume	Total volume in ml of Platelets administered in the first 4 hours (4h) from presentation.
24h Whole Blood Total Volume	Total volume in ml of Whole Blood administered in the first 24 hours (24h) from presentation.
24h pRBC Total Volume	Total volume in ml of Packed Red Blood Cells (pRBC) administered in the first 24 hours (24h) from presentation.
24h FFP Total Volume	Total volume in ml of Fresh Frozen Plasma (FFP) administered in the first 24 hours (24h) from presentation.
24h Platelet Total Volume	Total volume in ml of Platelets administered in the first 24 hours (24h) from presentation.
Total Whole Blood Volume	Total volume in ml of Whole Blood administered during hospital admission.
Total pRBC Volume	Total volume in ml Packed Red Blood Cells (pRBC) administered during hospital admission.
Total FFP Volume	Total volume in ml Fresh Frozen Plasma (FFP) administered during hospital admission.
Total Platelet Volume	Total volume in ml of Platelets administered during hospital admission.

Prophylactic and Therapeutic Anticoagulation

VTE Prophylaxis	Yes/No dropdown menu for if patient received venous thromboembolism (VTE) prophylaxis during hospital admission. Yes = patient received VTE prophylaxis during hospital admission. No = patient did not receive VTE prophylaxis during hospital admission.

Prophylactic and Therapeutic Anticoagulation (continued)

Timing of VTE Prophylaxis	If yes checked for VTE prophylaxis, numerical value for timing of initiation of VTE prophylaxis from admission (in hours).
Type of VTE Prophylaxis	If yes checked for VTE prophylaxis, single best choice for agent used for VTE prophylaxis. Options include: Enoxaparin Subcutaneous Heparin (SQH) Other
VTE Documented	Yes/No dropdown menu for if VTE was documented during hospital admission. Yes = VTE documented during hospital admission. No = VTE not documented during hospital admission.
VTE Type	If yes checked for VTE documented, single best choice for type of VTE. Options include: Pulmonary embolism (PE) Deep Vein Thrombus (DVT) Other
Therapeutic Anticoagulation	Yes/No dropdown menu for if the patient received therapeutic anticoagulation during hospital admission. Yes = patient received therapeutic anticoagulation during hospital admission. No = patient did not receive therapeutic anticoagulation during hospital admission.
Therapeutic Anticoagulation Agent	If yes checked for Therapeutic Anticoagulation, free text to best describe anticoagulation agent used (i.e. Warfarin, Therapeutic Enoxaparin, Heparin drip, etc.).

Outcome Data

Hospital LOS	Free text entry for number of consecutive days the patient was hospitalized at initial admission (in days). Day of admission = hospital day 1. (LOS = length of stay)
ICU LOS	Free text entry for number of consecutive days the patient required ICU admission (in days). ICU = Intensive Care Unit. Day of admission = hospital day 1. (LOS = length of stay)
Mortality	Yes/No dropdown menu for patient mortality. Yes = patient expired during initial hospitalization. No = patient did not expire during initial hospitalization.
Mortality Timing from Admission	If yes checked for Mortality, free text numerical value for time of death from admission (in days). Day of admission = hospital day 1.

Outcome Data (continued)

Readmission within 30 days	Yes/No dropdown menu for readmission within 30 days of hospital discharge. Readmission specifically for splenic or hepatic injury (not for concomitant injuries). Yes = patient readmitted within 30 days of initial discharge. No = patient not readmitted within 30 days of initial discharge.
Readmission CT scan	Yes/No dropdown menu for readmission CT scan. Yes = CT scan performed during readmission. No = No scan performed during readmission. If multiple scans were performed, select Yes.
Readmission CT scan findings	Free text entry for organ specific (splenic or hepatic) findings on readmission CT scan.
Intervention Performed on Readmission	Yes/No dropdown menu for intervention performed on readmission. Only include interventions performed for splenic or hepatic injury. Yes = intervention performed for splenic or hepatic injury on readmission. No = no intervention performed on readmission for splenic or hepatic injury.
Reason for Intervention on Readmission	Free text entry for reason for organ specific intervention upon readmission.
Type of Intervention on Readmission	Free text entry for type of intervention performed on readmission.